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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,627	12/08/2000	Karen L. Fincher	38-21(51770)B	8885

7590 12/01/2003

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EXAMINER	
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ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/01/2003

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 14

Application Number: 09/732,627
Filing Date: December 8, 2000
Appellant(s): Karen L. Fincher

Lawrence M. Lavin, Jr., and David Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 17 July 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

There were no responses filed subsequent to the Final Rejection in this case.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Patentability of claims 1 and 10-11 is discussed together as it relates to 35 U.S.C 101. Separate patentability of claims 1 and 10 is discussed as it relates to 35 U.S.C 112.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

Claims 1, 10, and 11 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific, substantial, and credible utility or a well established utility.

Claim 1 is directed to substantially purified nucleic acid molecule that encodes a cotton proteins or fragments thereof comprising a nucleic acid sequence of SEQ ID NO: 1. Claim 10 is directed to substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1. Claim 11 is directed to substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1.

The specification, including the sequence listing, provides the following information with respect to the claimed SEQ ID NO.

SEQ ID	Size	Type	Source
1	262 nt	cDNA	Gossypium hirsutum(cotton)

These sequences were cloned from a cDNA library (LIB3493) made from cotton male reproductive tissue from open flowers (androecium). (Specification page 26, lines 14-16; page 66, lines 15-16.) They are expressed sequence tags (ESTs).

The specification identifies no partial or full open reading frame encoding any protein or fragment thereof and none is apparent. (See claim 1 with limitations to encoding a cotton protein.) The specification does not assign any particular biological function to any protein that may be encoded by SEQ ID NO. 1 and none is apparent.

None of the other uses disclosed in the specification is particular to the claimed SEQ ID NO. 1 Rather, they are general to all.

All other uses disclosed are not deemed to be specific as using the nucleic acids for determining polymorphisms, molecular tags, expression studies, mapping, and so forth, are not particular to the claimed nucleic acid. General discussion of uses of nucleic acids does not meet the requirement for a specific utility. In addition, to reasonably confirm that full or partial protein sequences were encoded and determine how to use such proteins would require further experimentation and thus is not a substantial utility. Identifying and studying the properties of a nucleic acid to determine if it encodes a protein and then identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use.

For claims 10 and 11 which do not possess limitations with respect to encoding a protein, it remains a fact that the sequences claimed are uncharacterized pieces of DNA that cannot be used as molecular tags, in expression studies, mapping, and so forth, without further research and experimentation as to the identity and properties of the claimed SEQ ID NO. Basic research is required.

The uses disclosed by the specification are essentially to use the claimed nucleic acid as a laboratory reagent. Laboratory reagents must be sufficiently characterized and their properties

understood to be used in the manner disclosed in the specification. In the absence of such characterization, no meaningful information is provided. The claimed SEQ ID NO. is starting material for further research and not a research tool. It cannot be considered to be laboratory reagent in the form disclosed in the specification. Thus, no "immediate benefit to the public" is provided based upon the information disclosed in the specification. In all cases, experimentation on the sequence itself is required to further characterize it in order to use it in the manner disclosed. The only readily apparent *immediate* use for the disclosed EST is as an object of further scientific inquiry aimed at characterization of the EST itself in terms of identity of corresponding sequence polymorphisms (if any), map location, sequence and function of the corresponding mRNA and polypeptide, tissue distribution of the corresponding mRNA and encoded polypeptide, *etc.* These *immediate* uses are merely searches for a specific and substantial statutory utility for the claimed invention that fail to meet the statutory utility requirement. In *Brenner v. Manson*, 148 USPQ 689, 696 (US, 1966), the Court held that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing," and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." The original disclosure lacks any successful conclusion for even one of the vague and general utilities disclosed. Thus, no "substantial" or "real world" utility has been disclosed.

The limited information set forth in the specification with respect to SEQ ID NO: 1 is insufficient to establish a specific, substantial, and credible utility for the claimed nucleic acids.

Further, there is no evidence of a well-established utility for the disclosed EST or claimed nucleic acid molecule.

Claims 1, 10, and 11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 1 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

No partial or full open reading frame encoding all or part of a polypeptide is identified for any claimed SEQ ID NO. (See claim 1.) The claims encompass the nucleic acid for a gene (including introns and other non-coding information) within the scope of the invention by virtue of the "comprising" and "encoding" language. (See claims 1 and 10.) Neither the structural and functional properties of any gene comprising SEQ ID NO: 1 nor the structural and functional properties of any protein or fragment thereof encoded by a nucleotide sequence comprising SEQ ID NO: 1 is disclosed in the specification.

(11) Response to Argument

Appellant's arguments are addressed *seriatim*.

Section 8A

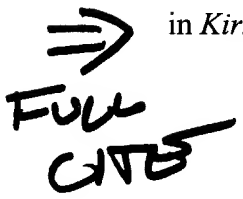
Appellants assert that the claimed invention meets the utility and enablement requirements because they have disclosed "nucleic acid molecules which, in their current form provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism in a population of corn plants." The examiner does not agree that the nucleic acid molecules provide any specific benefit to the public in their current form but rather require further experimentation to determine whether such a benefit can be found. Furthermore, the examiner fails to see how the identification of the presence or absence of a polymorphism in a population of corn plants is relevant to the disclosed SEQ ID NO.1, isolated from cotton.

Appellants also assert that the specification has provided an adequate description for nucleic acid molecules "comprising" or "consisting" the sequence of SEQ ID NO: 1 because the specification discloses SEQ ID NO: 1. The examiner does not agree that the structure of SEQ ID NO: 1 provides adequate description for claims "comprising" SEQ ID NO: 1, which encompass the nucleic acid for the gene or encoding proteins. Neither the structural and functional properties of any gene (including introns and other non-coding sequence) comprising SEQ ID NO: 1 nor the structural and functional properties of any protein or fragment thereof encoded by a nucleotide sequence comprising SEQ ID NO: 1 are disclosed in the specification. It is noted that the lack of written description rejection is directed to claims 1 and 10, which recite "comprising" and not to claim 11 reciting "consisting".

Section 8B

The Examiner agrees that the "The threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit," with the proviso that the benefit be "identifiable" in the original disclosure either as a specific assertion or being readily apparent from the disclosure (i.e. well established). Whether the instant application has met this burden is the subject of this appeal.

The specification generally teaches using the claimed polynucleotides to identify a polymorphism, but fails to teach that a polymorphism could in fact be detected, nor teaches a specific polymorphism that could be detected. The specification generally teaches using a polymorphism, detectable with the claimed nucleic acid molecules, as a molecular marker for a linked trait of interest, but fails to teach either the polymorphism or the trait of interest. The court in *Kirk* (at page 53) held:



> We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

The specification (page 30, first full paragraph) defines "polymorphism" as "a variation or difference in the sequence of the gene or its flanking regions that arises in some members of a species" (emphasis added). The following pages of the specification discuss various types of sequence polymorphisms and how they are detected. It is noted that on page 32 the specification states "By correlating the presence or absence of it [a polymorphism] in a plant with the presence or absence of a phenotype..." and on page 34 the specification states "Polymorphisms are useful, through linkage analysis..." Thus, the specification acknowledges that further analysis is

required to determine a use for a polymorphism even assuming one is found. A change of phenotype and correlation with phenotype must be found; linkage analysis must be performed.

Even to determine whether a polymorphism exists at a specific chromosomal location requires hybridization to at least two individual chromosomes, and generally involves analyzing genomic DNA from multiple members of a species; the specification discloses no such analysis. The specification fails to disclose: 1) whether the claimed nucleic acid molecule can in fact detect a polymorphism, or even whether such a polymorphism exists; and 2) at least one specific example of at least one of the types of polymorphisms described in the specification. The specification does not disclose any utility in this context for a nucleic acid molecule or EST that can NOT detect a polymorphism. Therefore, using the claimed invention to first determine whether or not the claimed nucleic acid molecule can, in fact, detect a polymorphism *is* to determine whether or not the claimed invention has a utility that requires detecting a polymorphism, i.e. it is "use testing" and not substantial. Since the specification fails to identify even one specific polymorphism that can be detected with the claimed nucleic acid molecule, the specification fails to show any specific correspondence between the disclosed general utility and the claimed subject matter, regardless of any specific application requiring detection of polymorphisms.

Appellants argue that the claimed nucleic acid molecules have utility as "probes for other molecules or as a source of primers." In particular, to use the claimed nucleic acid molecules to obtain a protein. The argument in the brief compares the claimed invention to a microscope.

A microscope is useful for determining structure of *any* sample of interest at the macroscopic, microscopic or molecular level, depending on the type of microscope. It is a

generally useful tool for a wide range of specific uses. One does not usually use a microscope to study related microscopes. In contrast, Appellant argues that the claimed nucleic acid molecules are useful to detect or measure nucleic acid molecules that possess a certain level of structural relatedness to the claimed nucleic acid molecules, the level of relatedness being defined by hybridization to the claimed nucleic acid molecules. However, the specification discloses *no* nucleic acid molecule that hybridizes with the claimed nucleic acid molecules that does *not* consist or comprise SEQ ID NO: 1or its complement. In order for hybridization between two nucleic acid molecules to occur, they must share at least some nucleotide sequence that is fully complementary. The length of fully complementary sequence required to detect hybridization depends primarily on the stringency of the specific hybridization conditions employed, the lower the stringency the shorter the length of fully complementary sequence required. The specification also fails to disclose any hybridization conditions required for detecting nucleic acid molecules that do *not* contain the nucleotide sequence of any of SEQ ID NO: 1 or its complements (other than subsequences of SEQ ID NO: 1), in addition to failing to disclose any source for such nucleic acid molecules.

All arguments pertaining to the utility of the claimed invention with respect to studying the corresponding genomic DNA and mRNA found in cotton, would also apply to any homologous nucleic acid molecules found in other plant species. In so much as the specification fails to describe a specific and substantial utility for the corresponding nucleic acids in cotton, so does it fail to describe a specific and substantial utility for the corresponding nucleic acids in other plant species.

Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* in support of their position that utility has been established. However, this decision is with respect to a mechanical device and not a laboratory reagent or research tool. Furthermore, applicant mischaracterizes the findings in this decision. This decision concerned claim interpretation and the CAFC found that the district court had erred in their interpretation of what the claim embraced and thus what was required to establish utility. The claimed device was found to fulfill the stated objective of mounting a stylus by the CAFC. These facts do not correspond to the instant specification

While the specification teaches (page 27, lines 1-2) that the claimed nucleic acid molecules "*may be employed* to obtain other nucleic acid molecules" (emphasis added), the specification does not indicate that any such nucleic acid molecules *had been* obtained, nor does it describe any characteristics possessed by such nucleic acid molecules. As to whether such molecules could, in fact, be obtained, the Office can neither prove nor disprove the assertion because the Office does not have laboratory facilities. At the time the application had been filed, future experimentation on the part of one skilled in the art would have been required to determine which, if any, other plant species contained nucleic acid molecules that could have been obtained using the claimed invention, and under what experimental conditions.

In this context, the claimed invention does not compare to a golf club, because one knows what a golf ball is and how to use the golf club to hit it, whereas the specification does not disclose or describe with particularity any known useful nucleic acid molecule that can be obtained, such as the corresponding promoter - it simply invites the skilled artisan to provide such information by further experimentation.

Substantial utility means that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate* benefit to the public," *Nelson v. Bowler*, 206 USPQ2d 881, 883 (CCPA 1980) (emphasis added). Since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one skilled in the art that it has been isolated, there can be no "*immediate* benefit to the public" in using the claimed nucleic acid molecule in this capacity; "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion," *Brenner* at page 696.

It is acknowledged that applicant has provided copies of references in support of arguments for similarity analysis in functional prediction. However, the fact remains that the specification provides no insight into the similarity of SEQ ID NO. 1 with any other known sequence. Instead it provides a blanket statement that this technology could be used, without actually providing evidence that it has been used for the SPECIFIC SEQ ID NO. 1.

With respect to credibility, appellant is reminded that in order to meet the requirements of 35 USC 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of well established utility, which would presume that the utility was credible). The claims have been rejected because 1) the specification fails to disclose at least one utility that is both specific and substantial, and 2) no convincing evidence has been presented to show that an EST, for which only its nucleotide sequence and source have been disclosed, has a well established utility.

Section 8C

The Examiner maintains that the uses asserted for the claimed invention are methods where the claimed invention is, itself, an object of scientific study, e.g. to determine whether the corresponding genomic DNA of cotton contains a polymorphism that can be detected with the claimed invention. The specification cannot enable or tell how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. The Examiner maintains that there is no patentable utility for the claimed invention for the reasons set forth above and thus the claims are not enabled.

Section 8D

The issue is whether Applicant was in possession of the genus being claimed (claims 1 and 10). This genus is not restricted to any particular disclosed subgenus or species, such as a vector comprising any of SEQ ID NO: 1 as an insert. The only nucleic acid molecules described by complete structure are those consisting of any of SEQ ID NO: 1. The only nucleic acid molecules comprising any of SEQ ID NO: 1- described in the specification by other characteristics are generic vectors comprising any of SEQ ID NO: 1. While it is acknowledged that Appellant need not describe "every nuance" of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of the entire genus being claimed. The genus of nucleic acid molecules being claimed embraces any and every type of nucleic acid molecule that comprises any of SEQ ID NO: 1 and additional sequences of any size and sequence, not just vector backbones. Clearly, at the time of filing, Appellant was not in possession of genomic materials that contain the common EST fragment, which are embraced by the open-ended

claims. The specification does not disclose what characteristics these additional sequences may or may not have that are consistent with the operability of the nucleic acid molecules as probes or primers for detection of SEQ ID NO: 1 in a target sequence, and all disclosed uses for the claimed nucleic acid molecules are fundamentally as probes or primers, at least in some aspect. The specification does not disclose encoding sequences or open reading frames (ORFs).

With respect to full length mRNAs, cDNAs and genomic sequences, one skilled in the art would reasonably conclude that the claims embrace these nucleic acid molecules, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising any of SEQ ID NO:1 and no other indication that would suggest Appellant possessed them. This particular subgenus embraced by the claims has a disclosed potential utility not possessed by those members of the claimed genus useful only in hybridization. Full length mRNAs, cDNAs and genomic sequences (genes) would encode the corresponding protein(s).

A fundamental issue here is specific to the very narrow class of product that is nucleic acid molecules. The basic question upon which Appellants and the Examiner disagree is whether the disclosure of a partial sequence of otherwise uncharacterized nucleic acid molecules that may encode a corresponding protein is sufficient to establish possession of a broad genus based solely on the description of the partial sequence, where the broad genus embraces the uncharacterized nucleic acid molecules by default. The subgenus of uncharacterized nucleic acid molecules that encode any corresponding protein is explicitly alluded to in the specification, and disclosed as possessing an additional use *not* possessed by any other members of the broad genus being claimed, i.e. encoding the protein. The specification fails to provide any structural or

functional characteristic for these desired nucleic acid molecules, which encode the protein, that would distinguish them from the other members of the genus, which simply comprise any of SEQ ID NO: 1 as the sole distinguishing feature. As stated in *University of California v. Eli Lilly and Co.* at page 1404:

> An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

That Appellants claims embrace nucleic acid molecules that encode a corresponding protein, whatever it may be, is clearly evident from the claim language chosen. The Court in *University of California v. Eli Lilly and Co.*, at page 1405, further noted regarding generic claims:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe* , 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .").

In the instant case, the only species specifically enumerated is the nucleic acid molecule of SEQ ID NO: 1 itself. The specific embodiments that in addition to SEQ ID NO: 1, include nucleic acids that will allow the corresponding protein to be encoded cannot be predicted without the coding sequence itself. This coding sequence has not been disclosed. Clearly, the specification would not show one skilled in the art that the these desired subcombinations were possessed by Appellant, and thus the embracing genus was also not possessed.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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October 15, 2003

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